UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE: INCRETIN MIMETICS PRODUCTS LIABILITY LITIGATION As to all related and member cases	MDL Case No.13md2452 AJB (MDD) ORDER: (1) GRANTING PLAINTIFFS' RULE 56(d) REQUEST FOR ADDITIONAL TIME FOR DISCOVERY; (2) DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT WITHOUT PREJUDICE, (Doc. No. 410); (3) DENYING DEFENDANTS' MOTION TO FILE UNDER SEAL, (Doc. No. 466); and (4) STRIKING THE CURRENTLY SEALED LODGED PROPOSED DOCUMENTS, (Doc. No. 442).

This multidistrict litigation (MDL) involves claims for personal injuries and/or wrongful death suffered by the "Injured Party" allegedly caused by one of four types of incretin-based treatments prescribed for diabetes mellitus type 2 ("type 2 diabetes"). Presently before the Court is Defendants' motion for summary judgment based on preemption and Plaintiff's request to deny or continue the motion to allow further discovery made pursuant to Federal Rule of Civil Procedure 56(d). For the following

reasons, Plaintiffs' Rule 56(d) request is GRANTED and Defendants' motion for summary judgment is DENIED without prejudice.

I. BACKGROUND [1]

According to the American Diabetes Association, type 2 diabetes is the most common form of diabetes with millions of Americans suffering from the disease. Type 2 diabetes is characterized by either the body's inability to produce enough insulin or the cell's inability to respond to the insulin. Insulin, a hormone produced by pancreatic beta cells, causes cells in the skeletal muscles and fat tissue to absorb glucose from the blood. When glucose builds up in the bloodstream instead of being taken into cells, the cells become starved for energy in the short term. Over time however, high blood glucose may lead to serious complications and damage to other parts of the body, including heart and blood vessel disease, nerve damage, and kidney damage among others.[2]

Defendants are four pharmaceutical companies (collectively "Defendants") that design, manufacture, market, advertise, distribute, promote, label, test, and sell incretin-based therapy drugs (the "Incretin Drugs"). Incretin-based therapies are used to lower blood sugar levels in adults with type 2 diabetes. These therapies are available in two families of medicines: dipeptidyl peptidase-4 (DPP-4) inhibitors and glucagon-like peptide-1 (GLP-1) analogs. Defendants are: (1) Amylin Pharmaceuticals, LLC ("Amylin") manufacturers of **Byetta**, the first to obtain Food and Drug Administration ("FDA") approval on April 28, 2005; (2) Eli Lily and Company ("Lilly") which collaborated with Amylin to promote Byetta.; (3) Merck Sharp & Dohme Corp. ("Merck-") manufacturers of **Januvia**, approved by the FDA on October 16, 2006, and **Janumet**, approved on March 30, 2007; and (4) Novo Nordisk Inc. ("Novo") manufacturers of **Victoza**, approved on January 25, 2010.

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[1] Factual allegations are taken from the Master Consolidated Complaint, (Doc. No. 202, Ex. A) and Defendants' memorandum of points and authorities in support of their motion for summary judgment, (Doc. No. 410.)

[2] *Type 2*, Am. Diabetes Assoc., http://www.diabetes.org/diabetes-basics/type-2/?loc=DropDownDB-type2

Plaintiffs in the MDL allege that as a proximate result of being prescribed and ingesting one of the four Incretin Drugs, the Injured Party was diagnosed with pancreatic cancer. (MCC at 5.) Accordingly, had the Injured Party or their physician been properly warned by Defendants regarding the risk of pancreatic cancer, the Injured Party's physician would not have prescribed the Incretin Drug and the Injured Party would not have ingested it. (*Id.*) Plaintiffs bring causes of action for: (1) strict liability; (2) strict products liability; (3) negligence; (4) breach of implied warranty; (5) breach of express warranty; (6) loss of consortium (as applicable); (7) wrongful death (as applicable); and (8) survival (as applicable) as well as claims for punitive damages. (*Id.* at 23-33.)

On August 26, 2013, the United States Judicial Panel on Multidistrict Litigation ordered the centralization of these actions in this Court. On April 17, 2014, Defendants moved for summary judgment arguing Plaintiffs' state law causes of action predicated on failure to warn are preempted by federal law. (Doc. No. 410.) Plaintiffs oppose arguing Defendants have not met their burden for this court to grant summary judgment based on impossibility preemption. Further, Plaintiffs request the Court to grant them an opportunity for further discovery pursuant to Rule 56(d) if Defendants' motion is not outright denied. (Doc. No. 443.)

II. LEGAL STANDARD

Rule 56(d) provides a device for litigants to avoid summary judgment when they have not had sufficient time to develop affirmative evidence. *Burlington Northern Santa Fe R. Co. v. Assiniboine and Sioux Tribes of Fort Peck Reservation*, 323 F.3d 767, 773 (9th Cir. 2003). "The general principle of Rule [56(d)] is that 'summary judgment should be refused where the nonmoving party has not had the opportunity to discover information that is essential to his opposition." *Price v. Western Resources, Inc.*, 232 F.3d 779, 793 (10th Cir.2000) (quoting *Anderson v. Liberty Lobby*, 477 U.S. 242, 250 n.5, 106 S. Ct. 2505 (1986)). District courts should grant a Rule 56(d) motion "fairly freely" where a summary judgment motion is filed before a party has had a realistic

opportunity to pursue discovery relevant to its theory of the case. *Burlington*, 323 F.3d at 773.

Pursuant to Rule 56(d), this Court has the discretion to either deny or continue a motion for summary judgment "if a party opposing the motion shows by affidavit that, for specified reasons, it cannot present facts essential to justify its position." Thus, this Court has discretion to continue this motion for summary judgment if opposing party needs to discover essential facts. *Cal. Union. Ins. Co. v. American Diversified Sav. Bank*, 914 F.2d 1271 (9th Cir.1990), *cert. denied*, 498 U.S. 1088, 111 S. Ct. 966 (1991). A party must show how additional discovery would preclude summary judgment and why a party cannot immediately provide "specific facts" demonstrating a genuine issue of material fact. *Mackey v. Pioneer Nat. Bank*, 867 F.2d 520, 523-24 (9th Cir. 1989). The party requesting a continuance must identify by affidavit the specific facts that further discovery would reveal, and explain why those facts would preclude summary judgment. *California v. Campbell*, 138 F.3d 772, 779 (9th Cir. 1998).

III. DISCUSSION

At this point in the litigation, discovery has been limited to the issue of general causation. (Doc. No. 325.) In its March, 4, 2014 Order, the Court required all "FDA files" relevant to the issue of general causation to be produced on or before May, 9 2014, 3 days prior to the deadline for Plaintiff's Opposition to the motion for summary judgment. At the May 28, 2014 case management conference, the Court was alerted to a dispute as to the scope of "all FDA files" as well as issues regarding the timely and complete production of discovery. With these matters in mind, the Court agrees with Plaintiffs that Defendant's motion for summary judgment is premature.

As stated above, where the party opposing a motion for summary judgment shows by affidavit or declaration, that, for specified reasons, it cannot present facts essential to justify its position, the court has discretion to deny or continue the motion. Plaintiffs have met this showing in the form of three declarations submitted.

As instructed by the Court's previous order on the production of discovery, Defendants complete responses were due on May 9, 2014, three days before Plaintiff's Opposition was due. Thus, Plaintiff's contention that they have not been afforded a meaningful opportunity to review the produced discovery has merit.[3] Moreover, the Court was informed on issues concerning the complete production of Plaintiffs' requested discovery. Plaintiffs have represented that around 50% of Defendants' responses made to their interrogatories state that the information will be provided at a future date. Additionally, the deadline for production of custodian files has been set for June 16, 2014. As it stands now, given that Plaintiffs lack the complete set of relevant evidence, it would be difficult for Plaintiffs to fully substantiate their position on the preemption issue.

Plaintiffs claim they must discover and review: (1) what Defendants knew about the association between the Incretin Drugs and pancreatic cancer; (2) what Defendants should have known about the association in light of available data; (3) what Defendants provided to the FDA regarding the association; and (4) what Defendants withheld from the FDA. (Declaration of Michael K. Johnson ("Johnson Decl.") Doc. No. 443, Ex. 101 at 8.) "This universe of documents and information includes the relevant information Defendants or third parties possess regarding preclinical, nonclinical, and animal studies, human studies, observational studies, post-marketing studies, adverse event reports, source documents for adverse event reports, and analysis of the data sets compiled by Defendants." (*Id.* at 4-5.) Plaintiffs have also alleged instances of under-reporting or misreporting by Defendants to the FDA. Such serious allegations require substantial evidence to support, and Plaintiffs must have a full opportunity to discover it, if indeed it exists. There have also been allegations on "missing" reports of known incidents of pancreatic cancer in connection with Byetta clinical trials. (Declaration of John M.

[3] It would have useful if Plaintiffs contacted chambers to alert the Court of this issue, however it is understandable given the complexity of this litigation and all the parties involved why this did not occur. The Court advises that in the future, if a deadline is approaching and a party has issues, to contact chambers and attempt to make an agreeable resolution first.

Restaino ("Restaino Decl.") Doc. No. 443, Ex. 103.) Plaintiffs have also highlighted the need for Defendants' internal communications with regards to their knowledge of the risk of pancreatic cancer. (Declaration of Neal L. Moskow ("Moskow Decl.") Doc. No. 443, Ex. 104.)

IV. MOTION TO FILE UNDER SEAL

Defendants' motion to file under seal exhibits attached to Plaintiff's Response is DENIED as moot, but without prejudice. (Doc. No. 466.) The Court will strike the relevant documents from the record.

V. CONCLUSION

It is conceivable that the existence of the documents sought will support Plaintiffs' position in opposing Defendants' summary judgment based on federal preemption. Accordingly, the Court, in its discretion, GRANTS Plaintiff's Rule 56(d) request. Defendants' motion for summary judgment based on preemption is DENIED without prejudice. The Court will confer with the Parties as to how much time is needed to complete the production and review of the pending discovery during the July 1, 2014 case management conference. In the meantime, counsel are ordered to meet and confer in person or by telephone, on plaintiff's need for discovery outside of the currently pending matters. The court is not opening the door to generalized discovery. Once the current general causation discovery, as well as any additional discovery the parties agree to or the Court orders, is complete, Defendant's may refile the Motion for Summary Judgment based on preemption.

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The Clerk of Court is instructed to strike the currently sealed lodged proposed documents filed under seal with the Court. (Doc. No. 442.)

IT IS SO ORDERED.

DATED: June 4, 2014

Hon. Anthony J. Battaglia
U.S. District Judge